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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/594,612	09/28/2006	Katsuyuki Tanizawa	HRK-002	1245
20374 7590 03/04/2009 KUBOVCIK & KUBOVCIK SUITE 1105 1215 SOUTH CLARK STREET ARLINGTON, VA 22202				
EXAMINER PENG, BO				
ART UNIT 1648		PAPER NUMBER		
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

**Application No.**

10/594,612

**Applicant(s)**

TANIZAWA ET AL.

**Examiner**

BO PENG

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 15 December 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) 8,11,12,14-16 and 18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7,9,10,13 and 17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 September 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 5/29/05&9/28/06.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

1. Applicant's election of Group I, without traverse, in the reply filed on December 15, 2008, is acknowledged. In the reply, Applicant has also elected species, without traverse, which are (1)(a) the lipid bilayer is derived from a yeast; (2) (c) the biorecognition molecule is an antibody; (3) (j) the molecule of Claims 13-16 is fluorescent, and (4) (o) the molecule (2) is bound to the biorecognition molecules. The requirement is deemed proper and is therefore made FINAL.
2. Accordingly Claims 1-18 are pending. Claims 8, 11, 12, 14-16 and 18 are withdrawn as non-elected. Claims 1-7, 9, 10, 13 and 17 are considered in this Office action.

### ***Foreign Priority***

3. Applicant's provision of foreign priority document Japan 2004-104702 filed on March 31, 2004, is acknowledged. It is noted, however, that an English translation has not been provided. Therefore, it is not clear whether the foreign priority document provides a written description for the instant claims. Applicant is reminded that such priority for the instant limitations requires written description and enablement under 35 U.S.C. 112, first paragraph. Therefore, the priority date is deemed to be the filing date PCT/JP2005/005803, March 29, 2005.

### ***Information Disclosure Statement***

4. The documents submitted in the information disclosure statement on May 29,

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2005, have been considered by the examiner with the exception of WO 00/73798A1, since it is not written in English. The information disclosure statement submitted on September 28, 2006, has not been considered by the examiner because the documents are not written in English, and an English translation is not provided.

***Claim Rejections - 35 USC § 112, second paragraph***

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 13 recites the limitation "one type of molecule" in the sensing tool of Claim 1. There is insufficient antecedent basis for this limitation in the claim. For the purpose of examination, Claim 13 is interpreted as: "The sensing tool according to claim 1 further comprises a molecule bound to the biorecognition molecule, wherein the molecule is consisting of fluorescent, luminescent, light absorptive, and radioisotope molecule."

***Claim Rejections - 35 USC § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-7, 9, 10 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated

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by Kuroda (EP 126255A1, Date of publication: 04.02.2002; cited in IDS).

9. Claims 1-7, 9, 10 and 17 are directed to a sensing tool comprising proteins capable of forming nanoparticles through the incorporation of a lipid bilayer and biorecognition molecules bound thereto (Claim 1), wherein the biorecognition molecules are covalent bound to the proteins (Claim 2), wherein the nanoparticles are hollow nanoparticles (Claim 3), wherein the proteins are virus surface antigen proteins (Claim 4), wherein the proteins are hepatitis B virus surface antigen proteins (Claim 5), wherein the proteins are capable of forming nanoparticles through the incorporation of a lipid bilayer derived from eukaryotic cells (Claim 6), wherein the proteins are capable of forming nanoparticles through the incorporation of a lipid bilayer derived from yeast (Claim 7), wherein the biorecognition molecules are molecules that control cellular functions, wherein the biorecognition molecules are antibodies, parts of antibodies, or antibody analogues (Claim 10), and the sensing tool employs a flat membrane-like array of biorecognition molecules comprising nanoparticles aligned on a substrate (Claim 17).

10. Kuroda teaches a hollow nanoparticle, comprising a protein particle obtained by expressing a protein in a eucaryotic cell, and a biorecognition molecule introduced thereto, wherein the eucaryotic cell is yeast cell, wherein the protein capable of forming a particle is a hepatitis B virus surface antigen protein, wherein the biorecognition molecule is a cell function-regulating molecule; wherein the biorecognition molecule is an antibody, see. e. g. Para [0009]-[0034], pp. 2-4 and particularly claims, p. 17. Kuroda exemplifies HBsAg particles comprising biorecognition molecule GFP, EGF, BTC, see e.g. Examples. These teachings anticipate Claims 1-7, 9 and 10. Moreover, Kuroda

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shows that HBSAg-GFP particles were cultivated in cells on 3.5 cm glass bottom Petri dishes (a substance), see e.g. Para [0051], which has implicitly shown that HBSAg-GFP particles “employ a flat membrane-like array of biorecognition molecules comprising nanoparticles aligned on a substrate”. This teaching anticipates Claim 17.

11. Claims 1-4, 6 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by McDonald (JBC, 159(3)441-452, 2002).
12. Claims 1-4 and 6 are summarized in Para 8. Claim 13 reads on the sensing tool of Claim 1 further comprises a molecule bound to the biorecognition molecule, wherein the molecule is a fluorescent molecule (elected species). (See Para 6 above for claim interpretation).
13. McDonald teaches HIV virions (nanoparticles) comprising HIV Vpr (biorecognition molecule) fused to the green fluorescent protein (GFP). HIV virions are known to comprise a lipid membrane molecules from host eukaryotic cells and virus surface proteins; see whole document, particularly Abstract. By combining GFP fused to the NH<sub>2</sub> terminus of HIV-1 Vpr tagged through other labeling techniques, it is possible to determine the state of progression of individual particles through the viral life cycle (sensor tool). Correlation of immunofluorescent and electron micrographs allowed high resolution imaging of microtubule-associated structures that are proposed to be reverse transcriptase complexes.
14. Since McDonald's HIV virions comprising Vpr-GFP meet the limitations of the claimed sensing tool, Claims 1-4, 6 and 13 are anticipated by McDonald.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

15. Claims 1-7, 9, 10, 13 and 17 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over Claims 1-16 and 18-27 of copending Application No. 10/509,249, and Claims 1-3 and 6 of co-pending application No. 11/987,476.
16. Claims 1-16 and 18-27 of copending Application No. 10/509,249 are directed to nanoparticles comprising HBsAg and an antibody to a cancer or a viral protein (biorecognition molecules).
17. Claims 1-3 and 6 of 11/987,476 are directed to a nanoparticle comprising HBsAg and a target-cell substance, specifically IFN or hepatocyte growth factor (biorecognition molecules),

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18. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims (genus) would be anticipated by the claims of 10/509,249 and 11/987476 (species).

19. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

***Remarks***

20. No claims are allowed.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bo Peng, Ph.D. whose telephone number is 571-272-5542. The examiner can normally be reached on M-F, 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, Ph.D. can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/BO PENG/

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